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09/760,917	01/16/2001	Mohamed M. Haq	650016-2	4854

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EXAMINER

NAJARIAN, LENA

ART UNIT	PAPER NUMBER
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3626

MAIL DATE	DELIVERY MODE
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01/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/760,917

Applicant(s)

HAQ, MOHAMED M.

Examiner

Lena Najarian

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15,23,30-34 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15,23,30-34 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 10/26/07. Claims 1, 2, 4, 6-9, 11, 12, 14, 15, 23, and 30-34 have been amended. Claims 1, 2, 4-15, 23, 30-34, and 36-38 remain pending.

Claim Objections

2. The objection to claim 33 is hereby withdrawn due to the amendment filed 10/26/07.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 4-11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 4, 6-9, 11, and 14 recite limitations for which there is no antecedent basis in the claims. In particular, the following passages lack or have vague antecedent basis:

(i) "the known patient-data": claim 4, line 4, claim 6, lines 3 & 5, claim 7, lines 3 & 5, claim 8, line 4, claim 9, line 4, claim 11, line 5, and claim 14, line 4.

6. Claims 5 and 10 incorporate the deficiencies of claims 4 and 9, through dependency, and are also rejected

7. The rejection of claims 1, 2, 4-15, 23, 30-34, and 36-38 under 35 U.S.C. 112, second paragraph, presented in the previous Office Action is hereby withdrawn due to the amendment filed 10/26/07.

Claim Rejections - 35 USC § 103

8. Claims 1-2, 4-8, 14-15, 30-34, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of Graettinger et al. (5,839,438).

(A) Referring to claim 1, Leet discloses a computer system for assisting a medical practitioner, comprising (abstract, col. 19, lines 20-24 and Fig. 1 of Leet):

means for receiving new patient data regarding a patient, a medical practitioner diagnosis regarding the patient, and a medical practitioner treatment plan for the patient (col. 18, lines 28-54 and Fig. 2 of Leet).

Leet does not expressly disclose:

means for accessing a standard diagnosis database to obtain standard diagnosis criteria corresponding to the medical practitioner diagnosis, with the new patient data including information related to said criteria, the standard diagnosis criteria identifying standard criteria for deriving a suggested diagnosis;

means for retrieving the suggested diagnosis from the standard diagnosis database;

means for comparing the medical practitioner diagnosis with the suggested diagnosis and for generating an alarm if there is a difference; and

means for communicating the diagnosis criteria and the alarm to the medical practitioner, thereby enabling the medical practitioner to retrospectively consider the appropriateness of the diagnosis.

Graettinger discloses means for accessing a standard diagnosis database to obtain standard diagnosis criteria corresponding to the medical practitioner diagnosis, with the new patient data including information related to said criteria, the standard diagnosis criteria identifying standard criteria for deriving a suggested diagnosis (col. 3, line 65 – col. 4, line 11 of Graettinger);

means for retrieving the suggested diagnosis from the standard diagnosis database (col. 8, line 64 - col. 9, line 6 and abstract of Graettinger);

means for comparing the medical practitioner diagnosis with the suggested diagnosis and for generating an alarm if there is a difference (col. 8, lines 19-26 of Graettinger); and

means for communicating the diagnosis criteria and the alarm to the medical practitioner, thereby enabling the medical practitioner to retrospectively consider the appropriateness of the diagnosis (col. 8, lines 19-26 and abstract of Graettinger).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Graettinger within Leet. The

motivation for doing so would have been to provide a "second opinion" that may confirm the physician's findings or point to ambiguities that call for a more detailed analysis (abstract of Graettinger).

(B) Referring to claim 2, Leet does not expressly disclose wherein the means for retrieving obtains the suggested diagnosis based upon the new patient data.

Graettinger discloses wherein the means for retrieving obtains the suggested diagnosis based upon the new patient data (col. 3, line 66 – col. 4, line 11 of Graettinger).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Graettinger within Leet. The motivation for doing so would have been to provide a "second opinion" that may confirm the physician's findings or point to ambiguities that call for a more detailed analysis (abstract of Graettinger).

(C) Referring to claim 4, Leet discloses wherein the medical practitioner treatment plan includes a prescription and the means for receiving further comprises:

a get drug data means for retrieving from a pharmacy one or more drugs in the prescription for the patient and from the known patient data identification of drugs that the patient is taking; and an interaction checking means for accessing a drug interaction database with (a) the one or more drugs in the prescription for the patient, (b) the drugs that the patient is taking, and (c) the prescription, to produce an alarm if there is an indication of an interaction (col. 18, line 49 – col. 19, line 12 of Leet; the Examiner

interprets “drug order” to be a form of “prescription” and “message” to be a form of “alarm”).

(D) Referring to claim 5, Leet discloses wherein the interaction checking means comprises mitigating means for suggesting methods to mitigate the interaction; and alternative recommendation means for suggesting alternative drugs with no interaction (col. 25, lines 18-61 of Leet).

(E) Referring to claim 6, Leet discloses wherein the means for receiving further comprises:

- a get patient data means for retrieving the known patient data; and

- a find treatment means for accessing a treatment protocol database and using a subset of the new patient data and a subset of the known patient data to determine a recommended treatment protocol (abstract of Leet).

(F) Referring to claim 7, Leet discloses wherein the means for receiving further comprises:

- a get patient data means for retrieving the known patient data; and

- a treatment search means for accessing a treatment recommendation database and using a subset of the new patient data and a subset of the known patient data to determine a treatment individualization recommendation (col. 12, line 50 – col. 13, line 1 of Leet).

(G) Referring to claim 8, Leet discloses wherein the medical practitioner treatment plan comprises a prescription and the means for receiving further comprises:

a get lab data means for obtaining laboratory results for the patient from a laboratory (col. 11, lines 36-40 of Leet); and

a find dosage means for using the laboratory results, a subset of the known patient data, the prescription and the new patient data in cooperation with a recommended dosage database to produce a recommended dosage for the prescription (col. 18, line 57 – col. 19, line 5 of Leet).

(H) Referring to claim 14, Leet discloses wherein the medical practitioner treatment plan comprises a prescription and the means for receiving further comprises:

a get drug data means for retrieving from a pharmacy one or more drugs prescribed for the patient and from the known patient data an identification of drugs that the patient is taking; and a drug cost means for accessing a drug cost database with (a) the one or more drugs prescribed for the patient, (b) the drugs that the patient is taking, and (c) the prescription, to produce an alarm if there is an indication that the patient is spending more on drugs than is necessary and to make a recommendation for a lower cost drug (col. 18, line 49 – col. 19, line 12 and col. 32, lines 35-49 of Leet).

(I) Referring to claim 15, Leet discloses wherein the means for receiving further comprises a check risks means for accessing a risk database to produce a risk reduction recommendation for the patient (abstract, lines 1-9 of Leet; the Examiner interprets “rankings” to be a form of “recommendation”).

(J) Referring to claim 30, Leet discloses wherein the means for receiving has access to one or more of the following:

a drug interaction database (col. 18, line 49 – col. 19, line 12 of Leet);

a treatment protocol database (abstract, lines 1-4 of Leet);
a treatment recommendation database (col. 1, lines 9-11 of Leet);
a recommended dosage database (col. 18, line 67 – col. 19, line 5 of Leet);
a drug cost database (col. 32, lines 35-49 of Leet); and
a risk database (abstract, lines 1-9 of Leet).

Insofar as the claim recites “one or more of,” it is immaterial whether or not all of the elements are disclosed.

(K) Referring to claim 31, Leet discloses further comprising an International Classification of Disease (ICD) determination means for processing a subset of the new patient data, a subset of the diagnosis and a subset of the medical practitioner treatment plan to determine an ICD (col. 1, lines 23-28, col. 7, lines 39-46, and Table 1 of Leet).

(L) Referring to claim 32, Leet discloses wherein the medical practitioner treatment plan comprises a prescription, an order, and an International Classification of Disease (ICD), and further comprising one or more of the following: a print prescription means for using the prescription to print a prescription form; an inform pharmacy means for using the prescription to inform a pharmacy of the prescription; a store data means for storing the new patient data on a hospital computer; an enter order means for entering the order in a physician order entry system; and a save ICD means for saving the ICD in a business office (col. 18, line 49 – col. 19, line 18 and col. 34, lines 16-18 of Leet).

(M) Referring to claim 33, Leet discloses a computerized method for providing assistance to a medical practitioner, the method comprising (abstract, col. 19, lines 20-24, and Fig. 1 of Leet):

receiving new patient data regarding a patient, a medical practitioner diagnosis regarding the patient, and a medical practitioner treatment plan for the patient from a medical practitioner by a personal communicator (col. 18, lines 28-54 and Fig. 2 of Leet).

Leet does not expressly disclose:

using a standard diagnosis criteria database to determine standard diagnosis criteria, the standard diagnosis criteria identifying standard criteria for deriving a suggested diagnosis from the standard diagnosis criteria database;

comparing the medical practitioner diagnosis with the suggested diagnosis;

generating an alarm to the medical practitioner in response to comparing upon a determination that the medical practitioner diagnosis does not match the suggested diagnosis;

communicating the standard diagnosis criteria and the alarm to the medical practitioner, thereby enabling the physician to retrospectively consider the appropriateness of the diagnosis.

Graettinger discloses using a standard diagnosis criteria database to determine standard diagnosis criteria, the standard diagnosis criteria identifying standard criteria for deriving a suggested diagnosis from the standard diagnosis criteria database (col. 3, line 65 – col. 4, line 11 of Graettinger);

comparing the medical practitioner diagnosis with the suggested diagnosis (col. 8, lines 19-26 of Graettinger);

generating an alarm to the medical practitioner in response to comparing upon a determination that the medical practitioner diagnosis does not match the suggested diagnosis (col. 8, lines 19-26 and abstract of Graettinger);

communicating the standard diagnosis criteria and the alarm to the medical practitioner, thereby enabling the physician to retrospectively consider the appropriateness of the diagnosis (col. 8, lines 19-26 and abstract of Graettinger).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Graettinger within Leet. The motivation for doing so would have been to provide a "second opinion" that may confirm the physician's findings or point to ambiguities that call for a more detailed analysis (abstract of Graettinger).

(N) Referring to claim 34, Leet discloses further including enabling, through the personal communicator, the following actions initiating implementation of the medical practitioner treatment plan and allowing the medical practitioner to revise the diagnosis or the medical practitioner treatment plan wherein initiating implementation of the medical practitioner treatment plan comprises informing a pharmacy of the prescription (col. 3, lines 55-66 and col 18, lines 54-57 of Leet).

Insofar as the claim recites "one or more of," it is immaterial whether or not the other features are disclosed.

(O) Referring to claim 36, Leet discloses wherein the step of comparing comprises the following actions: checking the appropriateness of prescribed medication; reviewing recommended treatment protocols; reviewing individualization recommendations; recommending dose adjustments; checking for adverse medication interactions; and checking the cost of prescribed medications (col. 3, lines 26-40 and col. 18, line 57 – col. 19, line 13 of Leet).

Insofar as the claim recites “one or more of,” it is immaterial whether or not all of the elements are disclosed.

(P) Referring to claim 37, Leet discloses accepting clinical notes regarding the patient (col. 3, lines 36-40 of Leet).

9. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of Graettinger et al. (5,839,438), and further in view of Portwood et al. (5,950,630).

(A) Referring to claim 9, Leet discloses wherein the medical practitioner treatment plan comprises a prescription and the means for receiving further comprises (col. 18, lines 49-57 of Leet):

a get drug data means for retrieving from a pharmacy one or more drugs prescribed for the patient and from the known patient data an identification of drugs that the patient is taking and foods the patient typically eats (col. 18, line 49 – col. 19, line 12 and Table IV of Leet; the Examiner interprets “diet” to be a form of “foods the patient typically eats”); and

an interaction checking means for accessing a database with (a) the one or more drugs prescribed for the patient, (b) the drugs that the patient is taking, and (c) the prescription and (d) the foods the patient typically eats, to produce an alarm if there is an indication of an interaction (col. 18, line 49 – col. 19, line 12 and Table IV of Leet; the Examiner interprets “drug order” to be a form of “prescription” and “message” to be a form of “alarm”).

Leet and Graettinger do not disclose that there is a drug/food interaction database.

Portwood discloses drug-food interaction tests (col. 6, lines 63-67 of Portwood).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Portwood within Leet and Graettinger. The motivation for doing so would have been to ascertain if the drug regimen is within recommended ranges and to determine if any drug/food interaction problems exist (col. 6, lines 59-61 of Portwood).

(B) Referring to claim 10, Leet discloses wherein the interaction checking means includes a recommendation means for recommending a drug that will not have an interaction (col. 25, lines 18-61 of Leet).

10. Claims 11-13 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of Graettinger et al. (5,839,438), and further in view of Evans (5,924,074).

(A) Referring to claim 11, Leet discloses wherein the medical practitioner treatment plan comprises a prescription and the means for receiving further comprises:

a get drug data means for retrieving from a pharmacy one or more drugs prescribed for the patient and from the known patient data identification of drugs that the patient is taking; and a checking means for accessing a database with (a) the one or more drugs prescribed for the patient, (b) the drugs that the patient is taking, and (c) the prescription, to produce an alarm if there is an indication of an interaction (col. 18, line 49 – col. 19, line 12 of Leet; the Examiner interprets “drug order” to be a form of “prescription” and “message” to be a form of “alarm”).

Leet and Graettinger do not disclose a radiology/drug interaction database and radiology tests.

Evans discloses the usage of x-rays when prescribing medications (col. 5, lines 13-22 of Evans).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet and Graettinger. The motivation for doing so would have been for the physician to obtain additional clinical data, such as x-rays before recommending a treatment plan (col. 5, lines 40-46 of Evans).

(B) Referring to claim 12, Leet and Graettinger do not disclose wherein the medical practitioner treatment plan comprises an order for X-rays and the means for receiving further comprises a check X-rays means for obtaining laboratory results from a laboratory and for accessing an X-ray contraindication database with the laboratory

results and the order for X-rays to produce a contraindication and to process the contraindication to produce an alarm.

Evans discloses wherein the treatment plan comprises an order for X-rays and the first means comprises a check X-rays means for obtaining laboratory results from a laboratory and for accessing an X-ray contraindication database with the laboratory results and the order for X-rays to produce a contraindication and to process the contraindication to produce an alarm (col. 5, lines 42-55, col. 12, lines 10-17 of Evans; the Examiner interprets "warning" to be a form of "alarm").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet and Graettinger. The motivation for doing so would have been to alert the physician to investigate the effects of the treatment (col. 12, lines 17-19 of Evans).

(C) Referring to claim 13, Leet and Graettinger do not disclose wherein the check X-rays means processes the contraindication to produce a recommendation.

Evans discloses wherein the check X-rays means processes the contraindication to produce a recommendation (col. 12, lines 10-34 of Evans).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet and Graettinger. The motivation for doing so would have been to allow the physician to investigate the effects of the medication and select another medication from the list (col. 12, lines 10-34 of Evans).

(D) Referring to claim 38, Leet and Graettinger do not disclose wherein accepting the clinical notes comprises recording a spoken rendering of the clinical notes.

Evans discloses wherein accepting the clinical notes comprises recording a spoken rendering of the clinical notes (col. 9, lines 1-4 of Evans; the Examiner interprets "physician's dictation" to be a form of "spoken rendering of the clinical notes").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet and Graettinger. The motivation for doing so would have been to include patient data in a variety of data types generated by healthcare providers (col. 8, lines 65-66 of Evans).

11. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of Graettinger et al. (5,839,438), and further in view of Barry et al. (6,081,786).

(A) Referring to claim 23, Leet and Graettinger do not disclose further comprising a personal communicator including a display having: a red alert area, where alarms regarding the potential for a major adverse effect are displayed; and a yellow alert area, where alarms regarding the potential for a minor effect or need for closer monitoring are displayed.

Barry discloses a personal communicator including a display having a red alert area, where alarms regarding the potential for a major adverse effect are displayed; and a yellow alert area, where alarms regarding the potential for a minor effect or need for closer monitoring are displayed (col. 14, lines 16-22 & 43-47 of Barry).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Barry within Leet and Graettinger. The motivation for doing so would have been to provide an instant graphical warning level (col. 14, lines 42-43 of Barry).

Response to Arguments

12. Applicant's arguments with respect to claims 1 and 33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a system and method for assessing physician performance (5,924,073) and systems and methods for electronic health management (US 2002/0010597 A1).

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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